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Proposed Registration Decision PRD2016-33

Tebuconazole

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Overview

Proposed Registration Decision for Tebuconazole

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is proposing full registration for the sale and use of Folicur Technical Fungicide and Mirage Stressgard, containing the technical grade active ingredient tebuconazole, for control of diseases of turfgrass on golf courses and sod farms.

Tebuconazole is currently registered for use as a seed treatment, for use on wheat, barley, oats, corn, nuts, cucurbits and soybeans and as a wood preservative. An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Folicur Technical Fungicide and Mirage Stressgard.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on tebuconazole use on golf courses and sod farms, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on tebuconazole use on golf courses and sod farms, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Tebuconazole?

Tebuconazole is the active ingredient in Mirage Stressgard, and it controls certain summer and winter diseases of turfgrasses on golf courses and sod farms.

Health Considerations

Can Approved Uses of Tebuconazole Affect Human Health?

Mirage Stressgard, containing tebuconazole, is unlikely to affect your health when used according to label directions.

Potential exposure to tebuconazole may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, tebuconazole was of slight acute toxicity via the oral and inhalation routes of exposure. Consequently, the signal word and hazard statement "CAUTION POISON" is required on the label. It is of low acute toxicity via the dermal route, non-irritating to the skin and minimally irritating to eyes. It does not cause an allergic skin reaction.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

The end-use product Mirage Stressgard was of low acute toxicity via the oral, dermal and inhalation routes of exposure, mildly irritating to the eyes and minimally irritating to the skin, and did not cause an allergic skin reaction. Based on these findings, the hazard signal words "CAUTION EYE IRRITANT" are required on the label.

Registrant-supplied short-term and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of tebuconazole to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints used for risk assessment included effects in the liver, spleen and the adrenal glands. There was an indication that the young animal was more sensitive than the adult animal. There was no evidence of carcinogenicity in rats after longer-term dosing with tebuconazole; however, an increase in liver tumours was noted in mice. The risk assessment protects against these and any other potential effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

No food residue data are required to support the registration of tebuconazole for use in/on turfgrass on golf courses and sod farms in Canada. However, due to the potential for residues to enter drinking water sources as a result of the turfgrass use, an aggregate dietary assessment was conducted to assess health risks from overall exposure to potential food residues from existing dietary uses and the current proposed use. Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than 1 year old, the subpopulation which would ingest the most tebuconazole relative to body weight, are expected to be exposed to less than 36% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from tebuconazole is not of health concern for all population subgroups.

Acute dietary (food plus drinking water) intake estimates for females 13-49 years of age were less than 59% of the acute reference dose, and are not of health concern.

As no food residue data are required to support the registration of tebuconazole for use in/on turfgrass on golf courses and sod farms in Canada, maximum residue limits (MRLs) are not required for this proposed use. For the MRLs currently established for this active ingredient on various crop commodities, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website.

Occupational Risks from Handling Mirage Stressgard

Occupational risks are not of concern when Mirage Stressgard is used according to the label directions, which include protective measures.

Workers who mix, load or apply Mirage Stressgard, as well as workers re-entering freshly treated golf courses and sod farms, can come in direct contact with tebuconazole residues on the skin. Therefore, the label specifies that anyone mixing/loading Mirage Stressgard must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves; and that anyone

applying Mirage Stressgard must wear a long-sleeved shirt and long pants. Workers that use handheld equipment (backpack sprayer and turf gun) for application must also wear chemical-resistant gloves. The label also requires that workers do not enter sod farms for 12 hours after application, and that workers and the general public do not enter treated areas in golf courses "until sprays have dried". Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the health risks to these individuals are not of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Risks in Residential and Other Non-Occupational Environments

Residential and non-occupational risks are not of health concern when Mirage Stressgard is used according to the label directions.

Adults, youth and children may be exposed to tebuconazole while golfing on courses treated with Mirage Stressgard. Based on the expected short- to intermediate-term duration of this activity, the health risk to children, youth and adults is not a concern. There are no residential turf uses of Mirage Stressgard.

Environmental Considerations

What Happens When Tebuconazole Is Introduced Into the Environment?

When used according to the label directions, tebuconazole is not expected to pose risks of concern to the environment.

Tebuconazole can enter non-target terrestrial habitats through spray drift, and it can enter non-target aquatic habitats through spray drift and run-off. It does not break down by reacting with light or water, but it can be broken down very slowly by microorganisms in soil and water, where it can persist. With repeated yearly ground applications, it will accumulate in the soil. As it readily binds to soil particles, it is not expected to reach groundwater. Tebuconazole can be dissolved in water, and once it reaches an aquatic environment, it will move through the water column and become deposited into the sediment layer, where it can remain for a considerable period of time.

Tebuconazole is unlikely to enter the atmosphere and be transported long distances from where it was applied. It is not expected to accumulate in plant and animal tissues.

Tebuconazole is found to be toxic to non-target terrestrial plants, amphibians, freshwater and marine/estuarine fish and invertebrates, freshwater plants and marine algae. It may cause adverse effects in these organisms if they are exposed to high enough levels; therefore, risk mitigation measures in the form of spray buffer zones (up to 5 m), use restrictions to help minimize carryover in soil and runoff into aquatic habitats, and precautionary label statements are used to minimize exposure and mitigate potential risks.

Value Considerations

What Is the Value of Mirage Stressgard?

Mirage Stressgard will control or suppress important summer and winter diseases on turfgrass.

Mirage Stressgard will control or suppress major turfgrass diseases, i.e., dollar spot, brown patch, anthracnose, fairy ring, summer patch, and pink and grey snow moulds. This end-use product will provide turf managers with a new group 3 fungicide active ingredient which can be used as a rotational option with other modes of action to control or suppress listed summer and winter turfgrass diseases, as well as contribute to resistance management.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Mirage Stressgard to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with tebuconazole on the skin or through inhalation of spray mists, anyone mixing/loading Mirage Stressgard must wear a long-sleeved shirt, long pants, shoes plus socks, and chemical resistant gloves, and that anyone applying Mirage Stressgard must wear a long-sleeved shirt and long pants. If the application is made with handheld equipment (backpack sprayer and turf gun) the workers must also wear chemical-resistant gloves.

The Mirage Stressgard label also requires that workers do not enter treated areas in sod farms for 12 hours after application, and that workers and the general public do not enter treated areas in golf courses "until sprays have dried". In addition, standard label statements to protect against drift during application are present on the label.

Environment

For field sprayer application on turfgrass, aquatic spray buffer zones of 5 m in width and terrestrial spray buffer zones of 2 m in width are required to protect sensitive aquatic and terrestrial habitats from spray drift of Mirage Stressgard.

Next Steps

Before making a final registration decision on tebuconazole, for control of diseases of turfgrass on golf courses and sod farms, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

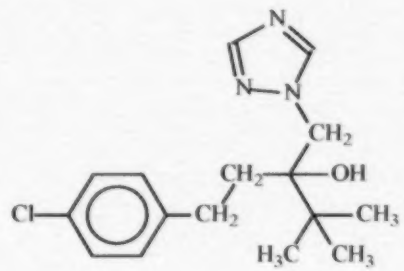
When the PMRA makes its registration decision, it will publish a Registration Decision on tebuconazole use on golf courses and sod farms (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Tebuconazole

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Tebuconazole
Function	Fungicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	*rac*-(3*R*)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)pentan-3-ol
2. **Chemical Abstracts Service (CAS)**	α-[2-(4-chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol
CAS number	107534-96-3
Molecular formula	$C_{16}H_{22}ClN_3O$
Molecular weight	307.8
Structural formula	
Purity of the active ingredient	97 %

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Folicur Technical Fungicide

Property	Result
Colour and physical state	white solid (powder)
Odour	characteristic odour
Melting range	104.7
Boiling point or range	not applicable

Property	Result
Density	1.25 g/mL
Vapour pressure at 20°C	1.3×10^{-3} mPa at 20°C
Henry's law constant at 20°C	1.434×10^{-10} atm-m^3- mol^{-1}
Ultraviolet (UV)-visible spectrum	For pH 4, 7 and 9, λmax ~ 221 nm with smaller peaks at 268 and 275 nm (0.0015% in acetonitrile-buffer) No absorbance at λ > 300 nm
Solubility in water at 20°C	32 mg/L
Solubility in organic solvents at 20°C	Solvent — Solubility (g/L) n-hexane — 0.08 toluene — 57 acetonitrile — 89 2-propanol — 99 1-octanol — 96 acetone — > 200 dichloromethane — > 200 dimethylformamide — > 200 dimethylsulfoxide — > 200
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} = 3.70
Dissociation constant (pK_a)	Tebuconazole will be uncharged at environmental pH
Stability (temperature, metal)	Thermally stable; no exothermic effect (decomposition) below 150°C. Compatible with glass, phenolic coated steel, brass, stainless steel, aluminum, Kraft paper and polyethylene after at least 6 weeks exposure at 40°C; not compatible with plain tinplate or plain steel.

End-Use Product—Mirage Stressgard

Property	Result
Colour	dark green
Odour	chalk like odour
Physical state	viscous liquid
Formulation type	suspension
Guarantee	240 g/L
Container material and description	High Density Polyethylene Jug
Density	1.110 – 1.150 g/mL
pH of 1% dispersion in water	8.98
Oxidizing or reducing action	Not expected to be an oxidizer, expected to be incompatible with strong oxidizers
Storage stability	Stable after accelerated storage for 14 days at 54 °C
Corrosion characteristics	Not corrosive to the container material
Explodability	Not expected to be explosive based on the nature of the ingredients

1.3 Directions for Use

Mirage Stressgard is applied in a foliar spray to turfgrass at a rate of 30 to 64 mL /100m^2 with a reapplication interval of 14 to 28 days. For pink and grey snow moulds, only one application before snow cover can be made. Tank mixes are also recommended.

1.4 Mode of Action

Tebuconazole is a demethylation inhibitor and belongs to the Fungicide Resistance Action Committee group 3 mode of action classification. The triazole fungicides are typically broad spectrum and exhibit rapid xylem-mediated translocation and rainfastness. It is considered to have a medium risk of resistance development.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and impurities in tebuconazole have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Please refer to Regulatory Note REG2006-11, *Tebuconazole* and Evaluation Reports under Application Numbers 2007-8784 and 2013-1019 for residue analytical methods for data generation and enforcement purposes.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for tebuconazole was conducted previously and is summarized in the Regulatory Note REG2006-11, *Tebuconazole* and Evaluation Reports under Application Numbers 2007-8784 and 2013-1019. No new toxicology data were provided for the current submission, apart from a rationale to bridge the acute toxicity data for the precedent product to support the end-use product Mirage Stressgard. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to tebuconazole.

Mirage Stressgard was determined to be toxicologically equivalent to the precedent product. Consequently, Mirage Stressgard is considered of low acute toxicity via the oral, dermal and inhalation routes of exposure in the rat and was mildly irritating to eyes and minimally irritating to the skin of rabbits. It was not a dermal sensitizer in guinea pigs.

Results of the toxicology studies conducted on laboratory animals with tebuconazole and the precedent product can be found in the Regulatory Note REG2006-11, *Tebuconazole*. New toxicological endpoints for risk assessment, relevant to the new product uses being reviewed in this submission, were established. For ease of reference, all the toxicology endpoints for use in the human health risk assessment are provided in this document, in Sections 3.3 and 3.4. The toxicological endpoints selected for risk assessment, can be found in Appendix 1, Table 1.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 11 May 2016, 13 human and 7 domestic animal incident reports involving tebuconazole have been reported to the PMRA.

The human incidents were determined to be related to the reported pesticide. Individuals were exposed to a tebuconazole either from the spray mist, the product splashing during mixing/loading, or accidental ingestion. The effects were minor in nature; eye irritation was the most common symptom reported. As "CAUTION EYE IRRITANT" is currently listed on the end-use product labels, no further action is required at this time.

Seven domestic animal incidents were considered to be related to the reported pesticide exposure. Animals (horses, dogs) were exposed as result of ingesting grains or plants treated with a tebuconazole product and experienced minor or moderate effects. In one case, product drifted onto a pond and two domestic koi fish died.

The incident report information was incorporated into the evaluation of tebuconazole and did not impact the risk assessment.

3.1.1 *Pest Control Products Act* Hazard Characterization

Please refer to the Evaluation Report under Application Number 2007-8784 for the *Pest Control Products Act* Hazard Characterization.

3.2 Determination of Acute Reference Dose

Females aged 13-49

The recommended acute reference dose (ARfD) for tebuconazole is 0.03 mg/kg bw, based on the NOAEL of 10 mg/kg bw/day in the mouse developmental toxicity study. The maternal effects at the LOAEL of 30 mg/kg bw/day were mild liver vacuolation, increased liver enzyme activity and post-implantation loss. Post-implantation loss could also be reflective of developmental toxicity. These findings were associated with an increased incidence of severe foetal

malformations including partial acrania at 30 mg/kg bw/day and runts, exencephaly, and cleft palate at 100 mg/kg bw/day. For the reasons outlined in the *Pest Control Products Act* Hazard Characterization section of the Evaluation Report under Application Number 2007-8784, the the *Pest Control Products Act* factor (PCPA) factor was retained but reduced from 10-fold to 3-fold, resulting in a composite assessment factor (CAF) of 300-fold.

The ARfD is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{10 \text{ mg/kg bw}}{300} = 0.03 \text{ mg/kg bw of tebuconazole}$$

General population (excluding females aged 13-49)
An acute reference dose for tebuconazole was not determined for the general population, including infants and children, because an endpoint of concern attributable to a single exposure was not identified in the oral toxicity studies for this population.

3.3 Determination of Acceptable Daily Intake

General population (including females aged 13-49)
The recommended acceptable daily intake (ADI) for tebuconazole is 0.03 mg/kg bw/day. Two 1-year dog studies were available for the assessment of chronic dietary exposure and the NOAEL from the study with a narrower dose range was selected. The most relevant NOAEL was 2.96 mg/kg bw/day, based on hypertrophy in the adrenal zona fasciculata and the presence of fatty vacuoles in the adrenal zona glomerulosa cells at the LOAEL of 4.39 mg/kg bw/day. This NOAEL is considered to be protective of the effects observed in the mouse developmental toxicity study. For this reason, it was considered appropriate to reduce the PCPA factor from 10-fold to 1-fold. Therefore, the composite assessment factor is 100-fold.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{2.96 \text{ mg/kg bw/day}}{100} = 0.03 \text{ mg/kg bw/day of tebuconazole}$$

This ADI provides a margin of 9300 to the dose at which liver tumours were observed in male and female mice in a dietary oncogenicity study and a margin of 1000 to the malformations observed in the mouse gavage developmental study in the presence of maternal toxicity.

Cancer Assessment

Please see the Evaluation Report under Application Number 2013-1019 for the cancer assessment.

3.4 Occupational Risk Assessment

3.4.1 Toxicological Endpoints

Short-term to intermediate-term inhalation
The NOAEL of 10 mg/kg bw/day in the mouse developmental toxicity study, based on increased malformations (partial acrania) and post-implantation loss, was considered to be the most relevant endpoint for short-term to intermediate-term occupational and bystander inhalation risk assessment. The worker population could include pregnant and lactating women and, therefore, it is appropriate to ensure adequate protection to the foetus or the nursing infant who may be exposed via their mother. In light of the concerns regarding prenatal and postnatal toxicity outlined in the *Pest Control Products Act* Hazard Characterization section of the Evaluation Report under Application Number 2007-8784, an additional factor of 3-fold, in addition to the standard factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, was applied. Therefore, the target margin of exposure (MOE) for these scenarios is 300. The selection of this study and this MOE is considered to be protective of all populations, including nursing infants and unborn children of exposed female workers.

Short-term to intermediate-term dermal
The NOAEL of 275 mg/kg bw/day from a mouse dermal developmental toxicity study was based on increased alanine transaminase (ALAT) activity in the liver and increased relative adrenal weights in the dams, and increased incidences of palatoschisis, bipartite sternebrae and non-ossification of the forelimb distal phalanx and supernumerary ribs in foetuses. Although two short-term dermal studies in rabbits had NOAELs of greater than 250 mg/kg bw/day and equal to 1000 mg/kg bw/day, respectively, these studies did not assess the endpoint of concern (malformations) observed in the mouse developmental toxicity study. The worker population could include pregnant and lactating women and, therefore, it is appropriate to ensure adequate protection to the foetus or the nursing infant who may be exposed via their mother. The target MOE of 300 includes the standard factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, and an additional factor of 3-fold applied for the reasons outlined in the *Pest Control Products Act* Hazard Characterization section of the Evaluation Report under Application Number 2007-8784. The selection of this study and target MOE is considered to be protective of all populations, including nursing infants and unborn children of exposed female workers.

Combined Inhalation and Dermal (Occupational)
Palatoschisis and exencephaly were common findings in the oral and dermal developmental toxicity studies in mice. No inhalation study was available that assessed these findings; therefore, an oral study was used as a surrogate, as it was assumed similar effects could occur by the inhalation route. To conduct a combined dermal and inhalation occupational exposure assessment, the NOAELs of 30 mg/kg bw/day from the mouse gavage developmental toxicity study and 275 mg/kg bw/day from the dermal mouse dermal developmental toxicity study were selected. The target MOE is 300, which includes a 10-fold uncertainty factor for interspecies extrapolation, a 10-fold uncertainty factor for intraspecies variability and a 3-fold database uncertainty factor for concerns related to potential sensitivity of the young.

Aggregate Risk Assessment

Short- and intermediate-term aggregate exposure to tebuconazole may be comprised of food, drinking water and residential exposure. The toxicological endpoint selected for aggregation for females 13-49 years of age was malformations. For the oral component, the NOAEL of 10 mg/kg bw/day from the oral developmental toxicity study in mice was selected with a target MOE of 300. For the dermal component, the NOAEL of 275 mg/kg bw/day from the dermal developmental study in mice was selected with a target MOE of 300. The PCPA factor for all routes was 3-fold as set out in the *Pest Control Products Act* Hazard Characterization section of the Evaluation Report under Application Number 2007-8784.

Occupational exposure to tebuconazole is characterized as short- to intermediate-term in duration, and is predominantly by the dermal and inhalation routes. Exposure to tebuconazole when golfing on treated turf is characterized as short- to intermediate-term in duration, and is predominantly by the dermal route.

3.4.1.1 Dermal Absorption

The dermal absorption value was not required in the calculation of dermal exposure, since the short- to intermediate-term dermal endpoint is based on a dermal toxicity study.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to tebuconazole when mixing/loading and application. Exposure to workers mixing, loading and applying Mirage Stressgard is expected to be short-to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Exposure estimates were derived for mixers/loaders/applicators applying Mirage Stressgard at the maximum rate in golf courses and sod farms using groundboom, backpack sprayer or turf gun.

The exposure estimates are based on mixers/loaders/applicators with the following personal protective equipment (PPE):

- a long-sleeved shirt and long pants, chemical-resistant gloves for all mixing/loading scenarios,
- a long-sleeved shirt and long pants for all application scenarios, and chemical-resistant gloves for backpack sprayer and turf gun.

As chemical-specific data for assessing human exposures were not submitted, dermal and inhalation exposures were estimated using the Pesticide Handlers Exposure Database (PHED), version 1.1 for workers involved with application using groundboom and backpack sprayers. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. Dermal and inhalation exposures for workers involved with low pressure handgun application were estimated using a study from the Outdoor Residential Exposure Task Force (ORETF).

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. A dermal absorption value was not required in the calculation of dermal exposure, since the short- to intermediate-term dermal endpoint is based on a dermal toxicity study. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. The dermal and inhalation exposure estimates were combined since they are both compared to the same toxicological endpoint of concern.

Exposure estimates were compared to the toxicological endpoints (no observed adverse effects level [NOAEL] of 275 mg/kg bw/day for dermal exposure and 10 mg/kg bw/day for inhalation exposure) to obtain the margin of exposure (MOE); the target MOE is 300 for both exposure routes. Table 3.4.2.1-1 presents the PHED and ORETF unit exposure values used and the estimates of exposure and risk for Mirage Stressgard. Calculated MOEs are above the target MOE of 300 for workers who wear the personal protective equipment stated on the product label, and are, therefore, not of concern.

Table 3.4.2.1-1: PHED and ORETF unit exposure estimates and Assessment for Chemical Handlers mixing/loading and applying Mirage Stressgard

Exposure scenario	PHED/ORETF unit exposure (µg/kg a.i.)[1]		ATPD (ha/day)[2]	Maximum application rate (kg a.i./ha)	Exposure (mg/kg bw/day)		Calculated MOE[5]			
	Dermal	Inhalation			Dermal[3]	Inhalation[4]	Dermal	Inhalation	Inhalation COM[6]	Combined Dermal + Inhalation[6]
Groundboom golf course	84.12	2.56	16	1.54	0.026	0.0008	10614	12683	37500	8250
Groundboom sod farm	84.12	2.56	30	1.54	0.049	0.00148	5661	6764	20270	4425
Turf gun	785	4.0	2	1.54	0.030	0.000154	9099	64935	194805	8000
Backpack sprayer	5445.85	62.10	0.25	1.54	0.026	0.000299	10493	3346	100335	9570

[1] Exposure was estimated for workers handling liquids and wearing a single layer plus gloves.

[2] Default area treated per day (ATPD) values for all but backpack sprayer; the value for backpack sprayer was calculated using the default 150 L/day from USEPA Policy No. 9 as follows: Based on a minimum application volume of 6 L/100 m^2 (range: 6-8 L water/ha; where 100 m^2 = 0.01 ha), the ATPD is: 150 L/day ÷ 600 L/ha = 0.25 ha

[3] Dermal exposure = (PHED unit-exposure × rate × ATPD × 0.001 kg/g × 0.001 mg/µg) / 80 kg bw

[4] Inhalation exposure = (PHED unit-exposure × rate × ATPD × 0.001 kg/g × 0.001 mg/µg × 100% inhalation absorption) / 80 kg bw

[5] Margin of Exposure (MOE) = $NOAEL_{(route\text{-}specific)}$ / Exposure
Based on dermal NOAEL of 275 mg/kg bw/day, target MOE = 300
Based on inhalation NOAEL of 10 mg/kg bw/day, target MOE = 300

[6] Common toxicological effects were observed for dermal exposure (based on the same NOAEL of 275 mg/kg bw/day for dermal exposure per se) and inhalation exposure (based on a higher NOAEL of 30 mg/kg bw/day than the 10 mg/kg bw/day for inhalation exposure per se). As such, the dermal and inhalation exposures can be combined; however, MOEs specific for inhalation exposure in determining combined exposures had to be calculated separately given the different NOAEL at which the effects were observed (i.e., 30 vs 10 mg/kg bw/day). Combined MOE = 1/[(1/inhalation MOE) + (1/dermal MOE)], where the inhalation MOE is based on the NOAEL of 30 mg/kg bw/day; and, where the dermal MOE is based on the NOAEL of 275 mg/kg bw/day; both MOEs are based on

malformations from developmental toxicity studies. The target MOE is 300 (all routes, durations).

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering golf courses and sod farms treated with Mirage Stressgard when conducting various activities. The duration of exposure is expected to be short-term for all re-entry activities. The primary route of exposure for workers re-entering treated areas would be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route, since tebuconazole is relatively non-volatile (1.3×10^{-6} Pa at 20°C) and as such, an inhalation risk assessment was not required.

No chemical-specific transferable turf residue (TTR) data were submitted. Postapplication risk assessments were conducted with the maximum rate of Mirage Stressgard. Dermal exposure to workers entering treated areas was estimated by coupling default TTR values (1% dislodgeable at Day 0, 10% dissipation per day) with activity-specific transfer coefficients and an exposure duration of 8 hours per day.

For postapplication risk, the dermal exposure estimates were compared to the toxicological endpoint (NOAEL = 275 mg/kg bw/day) to obtain the MOE; the target MOE is 300. Table 3.4.2.2-1 presents the calculated MOEs on the day of application and the resulting restricted entry intervals (REIs), which are not of concern.

Table 3.4.2.2-1: Postapplication exposure and risk estimates on the day of application for golf courses and sod farms treated with Mirage Stressgard

Re-entry activity	Peak DFR/TTR ($\mu g/cm^2$)[1]	Transfer coefficient (cm^2/hr)[2]	Dermal exposure (mg/kg bw/day)[3]	Calculated MOE[4]	REI[5]
Golf Course: Transplanting/Planting **Sod Farm**: Slab harvesting, Transplanting /Planting;	0.1892	6700	0.127	2169	Golf courses: Until spray has dried Sod farms: 12 hours
Golf Course: Mowing, watering, cup changing, irrigation, repair, miscellaneous grooming **Sod Farm**: Mowing, watering, irrigation	0.1892	3500	0.0662	4152	
Golf course and sod farm: Aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	0.1892	1000	0.0189	14533	

[1] Calculated using the default for turf of 1% dislodgeable on the day of application and 10% dissipation per day
[2] Transfer coefficients (TCs) from the Agricultural Reentry Task Force (ARTF)
[3] Exposure = (Peak DFR/TTR [$\mu g/cm^2$] × TC [cm^2/hr] × Exposure Duration (8 hours for workers) / (80 kg bw × 1000 µg/mg)
[4] Based on NOAEL of 275 mg/kg bw/day, target MOE = 300
[5] Restricted entry interval

3.4.3 Residential Exposure and Risk Assessment

3.4.3.1 Handler Exposure and Risk

Mirage Stressgard is not a domestic product; therefore, a residential handler assessment was not required.

3.4.3.2 Postapplication Exposure and Risk

Since Mirage Stressgard is for use on turfgrass in golf courses, there is potential for recreational postapplication exposure to the general population entering treated areas. The duration of exposure for golfing is considered to be short-term. The primary route of exposure for these individuals would be through the dermal route. Tebuconazole is considered non-volatile and it is not an inhalation concern for postapplication exposure.

Exposure was assessed according to equations and parameters stated in the 2012 USEPA Residential Standard Operating Procedures. Dermal exposure from golfing was assessed for adults (16 years plus), youth (11-<16 years) and children (6-<11 years) using default transferable turf residue (TTR) values (1% dislodgeable at Day 0, 10% dissipation per day) and the toxicological endpoint for short- to intermediate-term dermal exposure (NOAEL = 275 mg/kg bw/day). Table 3.4.3.2-1 presents the calculated MOEs on the day of application for recreational dermal exposure, which are above the target MOE of 300, and therefore, not of concern.

Table 3.4.3.2-1: Exposure and Risk Assessment for Golfers Entering Treated Turf Areas

Re-entry activity	Rate (kg ai/ha)	# Appls (min RTI)	Age Years)	Peak TTR ($\mu g/cm^2$)[1]	Transfer coefficient (cm^2/hr)[2]	Dermal exposure (mg/kg bw/day)[3]	MOE[4]
Golfing	1.54	2 appl (14 days)	16+	0.1892	5300	5.01E-02	5484
			11-<16	0.1892	4400	5.84E-02	4707
			6-<11	0.1892	2900	6.86E-02	4009

[1] Calculated using the default for turf of 1% dislodgeable on the day of application and 10% dissipation per day
[2] Transfer coefficients obtained from 2012 USEPA Residential SOP for golfer exposure.
[3] Exposure = (Peak TTR [$\mu g/cm^2$] × TC [cm^2/hr] × Exposure Duration (4 hours for golfers) / ([80 kg bw for adults, 57 kg bw for youths and 32 kg bw for children] × 1000 µg/mg)
[4] Based on NOAEL of 275 mg/kg bw/day, target MOE = 300

3.4.3.3 Aggregate Exposure

Tebuconazole is used on food crops as well as on golf courses. Since toxicological endpoints for short- to intermediate-term dermal exposure and chronic dietary exposure are the same, dermal exposure can be aggregated with chronic dietary (food plus drinking water) exposure.

Aggregate risk for females 13-49 years of age was calculated using the NOAELs of 10 mg/kg bw/day for dietary exposure and 275 mg/kg bw/day for dermal exposure. Table 3.4.3.3-1 presents the aggregate MOEs on the day of application, which are above the target MOE of 300, and therefore, not of concern.

Table 3.4.3.3-1: Aggregate Exposure from the Use of Mirage Stressgard

Population	Exposure (mg/kg bw/day)				Aggregate MOE[3]
	Dermal[1] (Golfing)		Chronic Dietary (Food + Drinking Water)[2]		
	Exposure	MOE	Exposure	MOE	
Females 13-49	0.0501	5484	0.003956	2528	1730

[1] Dermal exposure from Table 3.4.3.2-1 golfer subpopulation 16+.
[2] Chronic dietary (food + drinking water) exposure were derived from the DEEM-FCID calculator.
[3] Aggregate MOE = 1/[(1/oral MOE) + (1/dermal MOE)], where the oral MOE = oral NOAEL/dietary exposure, based on the NOAEL of 10 mg/kg bw/day; and, where the dermal MOE = dermal NOAEL/recreational dermal exposure, based on the NOAEL of 275 mg/kg bw/day, both based on malformations from the developmental toxicity study. The target MOE is 300 (both dermal and oral exposure routes).

3.4.3.4 Bystander Exposure and Risk

For Mirage Stressgard applied to turf in golf courses, the risk to bystanders is considered negligible as exposure to spray drift is expected to be well below the exposure for mixers/loaders and applicators.

3.5 Food Residues Exposure Assessment

3.5.1 Residues in Plant and Animal Foodstuffs

Please refer to Regulatory Note REG2006-11, *Tebuconazole* and Evaluation Reports under Application Numbers 2007-8784 and 2013-1019 for a summary of the previously reviewed data. The information captured herein only relates to the changes in dietary exposure due to the modification in the drinking water assessments to support the registration of tebuconazole for use on turfgrass in Canada.

3.5.2 Dietary Risk Assessment

Acute and chronic (cancer and non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™).

3.5.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic (cancer and non-cancer) analysis for tebuconazole: percent crop treated, default or experimental processing factors (where available), residues of treated crops based on supervised trial median residue (STMdR) values, United States Pesticide Data Program and Canadian Food Inspection Agency monitoring data, anticipated residues for all animal commodities and the yearly Estimated Environmental Concentrations (EECs) for groundwater based on the turf application rates. The refined chronic dietary aggregate exposure from all supported tebuconazole food uses and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to tebuconazole from food and drinking water is 13.7% (0.004044 mg/kg bw/day)] of the ADI for the total population. The highest exposure and risk estimate is for all infants less than 1 year of age at 35.9% (0.010624 mg/kg bw/day) of the ADI.

3.5.2.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the intermediate refined acute analysis for tebuconazole: percent crop treated, processing factors (default or experimental where applicable), MRLs or maximum residues in/on treated crops, anticipated residues for all animal commodities, and the daily EECs for groundwater based on the turf application rates. The intermediate refined acute dietary aggregate exposure for food and drinking water for all supported tebuconazole registered commodities is estimated to be 58.3% (0.019237 mg/kg bw/day) of the ARfD for females 13–50 years old (95th percentile, deterministic).

3.5.3 Aggregate Exposure and Risk

Given that turfgrass in golf courses can be treated with Mirage Stressgard, there is potential for exposure to tebuconazole through the diet, as well as activities related to golf. An aggregate risk assessment for tebuconazole was conducted to include the dietary exposure from food and drinking water sources and the dermal exposure from the use on golf courses. As noted in Sections 3.5.2.1 and 3.5.2.2, the aggregate exposure for female golfers, including the sum of the chronic dietary exposure and the dermal exposure incurred at the golf course for children, youth and adults are not of health concern.

3.5.4 Maximum Residue Limits

Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for tebuconazole.

The nature of the residues in animal and plant matrices, analytical methodology and residue trial data were assessed in Regulatory Note REG2006-11, *Tebuconazole* and Evaluation Reports under Application Numbers 2007-8784 and 2013-1019. The chronic (cancer and non-cancer) and acute dietary risk estimates are summarized in Appendix I, Table 2.

3.6 Concentrations in Drinking Water

EECs of tebuconazole in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. EECs of tebuconazole in groundwater were calculated using the Pesticide in Water Calculator (PWC) model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PWC are average concentrations in the top 1 m of the water table. EECs of tebuconazole in surface water were calculated also using the PWC model, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a vulnerable drinking water source, a small reservoir.

A Level 2 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing and geographic scenario for turf use only. Table 3.6-1 lists the application information and main environmental fate characteristics used in the simulations. A range of initial application dates spanning May-October were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 3.6-2 below.

Table 3.6-1: Major groundwater and surface water model inputs for Level 2 assessment of tebuconazole

Parameter	Value
Application Information	
Crop(s) to be treated	turfgrass (golf courses and sod farms)
Maximum allowable application rate per year (g a.i./ha)	3072
Maximum rate each application (g a.i./ha)	1536
Maximum number of applications per year	2
Minimum interval between applications (days)	14
Method of application	Ground, foliar
Environmental Fate Characteristics	
Hydrolysis half-life at pH 7 (days)	Stable
Photolysis half-life in water (days)	1144
Adsorption K_{OC} (mL/g)	543 (20th percentile of six K_{OC} values for tebuconazole)
Aerobic soil biotransformation half-life (days)	769 (one value available)
Aerobic aquatic biotransformation half-life (days)	1139 (one value available)
Anaerobic aquatic biotransformation half-life (days)	866 (one value available)

Table 3.6-2: Level 2 estimated environmental concentrations of tebuconazole in potential drinking water sources

Crop/use pattern	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Turfgrass (2 × 1536 g a.i./ha, at 14-day interval), yearly total of 3072 g a.i./ha	113	113	50	41

1 90th percentile of daily average concentrations
2 90th percentile of 365-day moving average concentrations
3 90th percentile of the peak concentrations from each year
4 90th percentile of yearly average concentrations

Water Monitoring Data

Water monitoring information was available for tebuconazole from Ontario, Quebec, Nova Scotia, Manitoba, British Columbia (BC) and the United States.

In general, sampling occurred in use areas and during the summer months when tebuconazole would be applied. Based on available monitoring data, with a few exceptions from BC and Ontario in 2003, tebuconazole is seldom detected in water across Canada and the United States.

A total of 6810 groundwater samples were analyzed for tebuconazole in Canada and the United States, with the vast majority of the samples being from the United States. Tebuconazole was detected in only 15 of the samples and the maximum concentration detected was 0.166 µg/L, from an American sample. Tebuconazole was only analyzed in a total of 11 groundwater samples from Canada. The maximum concentration detected in Canadian groundwater was 0.00087 µg/L.

A total of 4322 samples of treated water or bottled water were analyzed for tebuconazole, all of which were from the United States. There were no data for Canada. Tebuconazole was detected in 78 of the samples (<2%), and the maximum concentration measured was 0.15 µg/L.

A total of 14989 ambient surface water samples were analyzed for tebuconazole residues in Canada and the United States. Of these, tebuconazole was detected in 964 of the samples analyzed (6%). The maximum concentration of tebuconazole residues detected was 3.28 µg/L from a sample taken in Minnesota. Considering Canadian data only, tebuconazole was detected in ambient surface water in 18 out of the 289 water samples analyzed (6%). In Canada, the highest concentration of tebuconazole in surface water was 0.0128 µg/L, detected in BC.

Overall, based on available monitoring data, tebuconazole is seldom detected in water across Canada and the United States. The maximum concentration of tebuconazole detected in potential drinking water sources was 3.28 µg/L, from a surface water sample collected in the United States. The relatively small number of samples and low detection frequencies in Canada preclude the use of an EEC based on Canadian monitoring data for acute and chronic drinking water exposure.

4.0 Impact on the Environment

The fate and environmental behaviour of tebuconazole, as well as its impacts on non-target terrestrial and aquatic organisms, have been previously assessed for foliar use on agricultural crops (for details see Regulatory Note REG2006-11, *Tebuconazole*). An updated environmental assessment was conducted in support of tebuconazole application to turfgrass.

4.1 Fate and Behaviour in the Environment

The physico-chemical properties of tebuconazole and its environmental behaviour were characterized previously (REG2006-11, *Tebuconazole*). Subsequently reviewed environmental fate data include a Canadian field dissipation study on bare soil plots, which was submitted to

meet the requirements of full registration for foliar uses (See Appendix 1, Table 3 for a summary of endpoints). The Canadian study incorporated applications for three consecutive years. Tebuconazole was persistent and carried over, though the dissipation half-lives did decrease for each of the three years. Two additional American terrestrial field dissipation studies conducted on turf plots in eco-regions relevant to Canada were voluntarily submitted and reviewed in support of the major new use on turf.

The two U.S. studies conducted in ecoregions relevant to Canada were conducted on turf plots rather than bare soil plots. The presence of a thatch layer at the turf-soil boundary created an alternate dissipation route, so dissipation times on turf are not directly comparable to previous values determined on bare soil. Despite being conducted on turf, the studies still demonstrated the persistence of tebuconazole in the upper soil layers (0 – 15 cm), significant carry over into the next growing season, as well as the presence of the minor soil transformation product: 1,2,4-triazole (identified in previous reviews) at low levels.

A summary of the results from the Canadian terrestrial field dissipation study and the American studies relevant to the Canadian use pattern can be found in Appendix 1, Table 3.

4.2 Environmental Risk Characterization

A comprehensive environmental risk assessment for non-target terrestrial and aquatic organisms with respect to the foliar use of tebuconazole on agricultural food crops was previously conducted. EECs for the current risk assessment were derived from the known environmental behaviour of tebuconazole along with the rates and application methods for the new use pattern on turf. The effects concentrations (e.g., LD_{50}, EC_{25}, NOEL, etc.) were taken from the ecotoxicological data for the identical suite of representative non-target organisms as in the previous assessment (REG2006-11, *Tebuconazole*). Additional data for non-target terrestrial plants, chironomids, marine fish and algae were submitted and evaluated subsequent to these two published reviews, and are also included.

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. EECs are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (e.g., direct application at a maximum cumulative application

rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

The current risk assessment incorporates the largest seasonal maximum use rate currently proposed for Mirage Stressgard (two applications of 1536 g a.i./ha, with a minimum 14 day interval, for a total of 3072 g a.i./ha). This application rate was chosen for the screening level risk assessment because it represents the most conservative use pattern. The new maximum use rate was used to calculate updated EEC values, which can be found in Appendix 1, Table 4.

4.2.1 Risks to Terrestrial Organisms

Terrestrial organisms such as earthworms, honeybees, birds, small wild mammals and terrestrial vascular plants may be exposed to tebuconazole-containing end use products in the environment through direct contact with treated material, contact with spray drift, or from ingestion of contaminated food.

The most sensitive ecotoxicity endpoints for these non-target terrestrial organisms along with the EECs derived from the seasonal maximum use rate on turf were used in the current risk assessment. Updated ecotoxicity endpoint values and those derived from new study data can be found in Appendix 1, Table 5. Whereas the screening level assessment assumes direct overspray onto a terrestrial habitat, or in the case of dietary exposure – a completely contaminated food source; the refined assessment identifies the risk from tebuconazole spray drift onto adjacent habitats and a wider range of dietary exposure scenarios. At the screening level, the EEC for direct on-field application was considered for all representative groups of terrestrial organisms: invertebrates, plants, birds and mammals. During refined risk assessment, EECs for non-target sites immediately adjacent to the treatment site (e.g., off-field) were also considered for plants, birds and mammals. Off-field EECs are calculated using the percent deposition expected at a point one metre downwind from the application site. The percent off-field drift expected is 6% for medium droplet size of field sprayer equipment, which is the one that is typically used for systemic fungicides.

For a summary of RQ values for non-target terrestrial organisms, see Appendix 1, Table 7 - terrestrial earthworms and plants: Screening Level, Table 8 – terrestrial plants: drift , Table 9 – Birds and Mammals: Screening Level, Table 10 – Birds: Expanded Assessment, Table 11 – Mammals: Expanded Assessment.

Earthworms and Honeybees: The proposed seasonal maximum use rate of Mirage Stressgard for multiple applications (3072 g a.i/ha) does not exceed the level of concern for terrestrial invertebrates including earthworms and honeybees.

Terrestrial Vascular Plants: The plant ecotoxicity study that was identified as an outstanding data requirement in ERC2006-11 was reviewed and found to be acceptable in satisfying the requirement for trials that compare results from the use of the pesticide plus surfactant against results from the use of the pesticide alone (See Appendix 1, Table 5 for summary of endpoints for seedling emergence).

The risk to non-target terrestrial plants was determined by comparing the maximum application rates of tebuconazole with the revised EC_{25} of 63.3 g a.i./ha for biomass reduction in seedling emergence, and an EC_{25} of 453 g a.i./ha for vegetative vigour as reported in REG2006-11, *Tebuconazole*. The LOC is exceeded at the screening level for Mirage Stressgard for both seedling emergence and vegetative vigour. When drift is taken into account (projected deposition of 6%), the LOC is no longer exceeded for vegetative vigour, though it is still exceeded for seedling emergence. Due to the exceedance of the LOC at the screening level, a precautionary label statement and terrestrial buffer zones are required (Appendix 1, Table 17).

Birds and Mammals: The risk to birds from tebuconazole exposure on an acute basis is expected to be low. Calculated risk quotients for acute effects at the screening level do not exceed the LOC for large birds. Although they do exceed the LOC for small and medium birds, it is only by a small margin (RQs = 1.34 and 1.04). This risk occurs only with maximum nomogram residues (all RQs for mean nomogram residues are ≤ 1), and it only occurs for on-field exposure. Once spray drift is taken into account, all off-field RQs are ≤ 0.05.

Tebuconazole may pose a risk to birds on a reproductive basis. Calculated risk quotients for reproductive effects at the screening level exceed the LOC for all three size groupings. Thus, the risk for adverse effects was further characterized by including a range of tebuconazole residue concentrations on all relevant food items. The reproductive LOC is not exceeded for off-field exposure, though it is exceeded for on-field exposure. When considering both maximum and mean nomogram residues, the LOC for on-field exposure is exceeded for the two feeding guilds that are most relevant to turf uses (insectivores and herbivores that may be found foraging in and around turf plots). Although the reproductive risks from the on-field exposure of multiple applications of tebuconazole cannot entirely be ruled out, birds would need a large amount of highly contaminated food items to elicit adverse effects on reproduction. Under actual conditions, a variety of contaminated and uncontaminated food items is likely to be consumed.

For mammals, the pattern of risk is similar as that for birds: adverse effects resulting from acute exposure are not expected, though there is a potential for reproductive effects based on chronic exposure. The acute RQ values are all below LOC (both on-field and off-field, using both maximum and mean nomogram residues). Conversely, the reproductive RQ values for on-field exposure are all above LOC for all size groupings and for several feeding guilds – including insectivores and herbivores – those that are most relevant to turf uses.

When the bird and mammal ecotoxicity and risk information is taken as whole, it is possible that tebuconazole may pose a reproductive risk to wild bird and small mammal foraging on treated turf plots, thus, a precautionary label statement is required.

4.2.2 Risks to Aquatic Organisms

The aquatic toxicity endpoints reported in REG2006-11, *Tebuconazole* are used in the current aquatic risk assessment. The data that were identified as outstanding requirements (a chronic toxicity study of tebuconazole to a sediment dwelling aquatic organism and an acute study on marine/estuarine fish) were subsequently reviewed in support of the conversion to full registration for foliar uses. An acute study on the marine diatom was subsequently reviewed as well. The additional endpoints derived from these three studies (Appendix 1, Table 6) are included in this assessment.

Although the proposed use on turf does not include direct application to water, the possibility that aquatic systems will be exposed cannot be ruled out. Tebuconazole may enter the aquatic environment through spray drift and/or runoff. The most sensitive ecotoxicity endpoints for the representative non-target aquatic organisms along with the proposed turf use pattern were used in the screening level risk assessment, assuming a direct overspray to a water body. In those cases where the screening level assessments resulted in the LOC being exceeded, a refined assessment was conducted to further characterize the risk from drift and runoff exposure into aquatic habitats.

Risk quotient values were calculated using the aquatic EECs (Appendix 1, Table 4) and the appropriate ecotoxicological endpoints of interest for the suite of representative non-target aquatic organisms. The resulting RQ values for the multiple applications scenario at the screening level (Appendix 1, Table 12) reveal that the level of concern due to tebuconazole exposure is not exceeded for *Daphnia magna*, juvenile stages of rainbow trout and bluegill sunfish, freshwater green algae, marine oyster, and marine fish on an acute basis and for chironomids on a chronic basis. On the other hand, the level of concern is exceeded for *Lemna gibba*, mysid shrimp and marine algae on an acute basis and for *Daphnia magna*, rainbow trout (ELS), and marine fish on a chronic basis. It is exceeded for amphibians (using rainbow trout as surrogate data) on both an acute and chronic basis. Where the LOC is exceeded, the RQ values range from 1.27 for acute exposure of mysid shrimp to 170 for chronic exposure of amphibians.

During the initial screening level assessment, the aquatic EEC value used in the RQ calculation is based on the assumption that exposure is derived from a direct overspray to an aquatic habitat, that is, 100% deposition. Therefore, the EEC value can be refined by considering the percent deposition at one metre downwind of application. For systemic fungicides, this is typically a medium spray quality and is projected to be 6% deposition for ground application. Applying the adjustment for expected spray drift, the resulting refined RQ values decrease to below the level of concern for *Daphnia magna*, *Lemna gibba*, amphibians, mysid shrimp, marine fish and marine algae. Thus, the level of concern from spray drift is still exceeded for the two remaining groups of sensitive organisms: rainbow trout ELS (RQ = 1.9) and amphibians on a chronic basis (RQ = 10.2). The RQ values refined for drift are presented in Appendix 1, Table 13.

The potential for adverse effects on sensitive aquatic organisms resulting from surface runoff from areas treated with tebuconazole was characterized. Both modelling estimates and available water monitoring data were considered for the determination of run-off EECs. A total of 15126 water samples analyzed for the presence of tebuconazole in Canada and the United States. Tebuconazole was detected in 967 samples (6%). Considering Canadian data only, tebuconazole was detected in 18 out of a total of 393 water samples (5%). The analysis revealed that the highest concentration of tebuconazole detected in water (3.28 µg/L) from a surface water monitoring sample in the United States, is lower than the peak concentrations predicted by modelling for water bodies 80 cm and 15 cm deep in Canada (Appendix 1, Tables 14 and 15). The second highest detection (3.24 µg/L) was from a surface water sample taken in California. Considering Canadian data, the highest concentration of tebuconazole detected was 0.036 µg/L from a surface water sample taken in BC. The relatively small number of samples and low detection frequencies in Canada preclude the use of an EEC based on Canadian monitoring data. Thus, it was determined that the values generated through modelling are better suited for use in the aquatic risk assessment.

In order to assess the risk, the EEC for the appropriate water depth and time frame was compared to the ecotoxicity of tebuconazole for the organisms of interest (Appendix 1, Table 16).

Using the aquatic EECs from the Level 1 modelling for the multiple applications scenario (1536 g a.i./ha × 2 apps), the calculated risk quotients did not exceed the level of concern for *Daphnia magna*, amphibians, and mysid shrimp, all on an acute basis. However, the LOC was exceeded for the remainder of the aquatic organisms identified: early life stages of freshwater fish (rainbow trout), freshwater vascular plants (*Lemna gibba*), marine fish (sheepshead minnow) and marine algae (diatom). The risk quotients range from 1.1 (sheepshead minnow – acute) to 12.8 (amphibians – chronic). The second most sensitive organism is the early life stages of fish (RQ = 8.8).

Due to the exceedance of the level of concern for sensitive aquatic organisms from both spray drift and runoff, aquatic spray buffer zones and mitigative label statements will be required on the new end-use product label for Mirage Stressgard (Appendix 1, Table 17).

4.2.3 Environmental Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to Canadian health or the environment. No environmental incidents relating to the active ingredient tebuconazole were found in the PMRA database.

The USEPA's Ecological Incident Information System (EIIS) was also queried for environmental incidents related to tebuconazole that were available in that database up to October, 2015. The EIIS database contains 16 incident reports of adverse effects that were at least possibly related to exposure to tebuconazole. The majority of these cases involved damage or death of peanut, spring wheat, and soybean crops. One additional incident was found (for fish mortality) which was relevant to the Canadian use pattern on turf. An unknown number of fathead minnows inhabiting a stretch of creek were affected, and the incident was only possibly linked to tebuconazole exposure. The toxicity of tebuconazole to fish has previously been

established and this information has been considered in the evaluation of Tebuconazole Technical Fungicide and in the mitigation measures for the new end-use product, Mirage Stressgard.

5.0 Value

5.1 Consideration of Benefits

The registration of Mirage Stressgard will provide turf managers with a new and effective group 3 active ingredient which can be used as a rotational option with other mode of action fungicides to control or suppress listed summer and winter turfgrass diseases, as well as contribute to resistance management. There are currently many other conventional (fungicide groups 1, 2, 3, 7, 11, 12, M, U) and non-conventional (*Bacillus subtillis,* mineral oil) fungicides registered for control or suppression of the listed diseases.

5.2 Effectiveness Against Pests

Value information was submitted in the form of efficacy trials as well as use history of the product in the United States. It was demonstrated in the efficacy trials and use history that tebuconazole is effective in controlling dollar spot, brown patch, anthracnose, fairy ring, summer patch, and grey snow mould. Tebuconazole also provided suppression of pink snow mould or control when applied in tank mixes with other products. Tank mixes are also recommended for control of grey snow mold.

5.3 Non-Safety Adverse Effects

Mirage Stressgard, when applied as directed, will not adversely affect turfgrass quality or cause phytotoxicity, as demonstrated in the efficacy trials.

5.4 Supported Uses

The reviewed value information was sufficient to support the claims on the Mirage Stressgard label. Details of the supported uses are provided in Appendix 1, Table 18.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the formal review process (REG2006-11, *Tebuconazole*), tebuconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria (See Section 8 in REG2006-11, *Tebuconazole* for more details). The previously published TSMP conclusions apply to the current submission:

- Tebuconazole does not meet all the Track 1 criteria
- Tebuconazole does meet the Track 1 criterion for persistence because the DT_{50} values in soil (769 days) and water (1139 days), do exceed the Track 1 criterion for soil and water.
- Tebuconazole does not meet the Track 1 criterion for bioaccumulation, as its octanol-water partition coefficient (log K_{ow} = 3.7) is below the Track 1 criterion and the BCF values in fish were 13 (edible), 150 (viscera), 78 (whole fish).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the current review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade tebuconazole does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.
- The end-use product Mirage Stressgard contains the preservative 1,2-benzisothiazoline-3-one at 0.05% which contains low levels of dioxins and furans. These are being managed as outlined in the PMRA Regulatory Directive DIR99-03 for the implementation of TSMP.

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

6 Canada Gazette, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

7 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

8 DIR2006-02, PMRA Formulants Policy.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[4].

Table 6 – 1 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints[5]
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life < 182 days	Yes 770 days (aerobic soil DT_{50})
	Water	Half-life ≥ 182 days	Yes 1386 days (whole system DT_{50})
	Sediment	Half-life ≥ 365 days	Yes 1386 days (whole system DT_{50})
	Air	Half-life ≥ 2 days or evidence of long range transport	No Non-volatile (vapour pressure = 1.3×10^{-6} Pa; 1.275×10^{-8} mm Hg). Not volatile from water and moist surfaces (Henry's Law Constant (1.434×10^{-10} atm-m^3-mol^{-1}).
Bioaccumulation[4]	Log $K_{OW} \geq 5$		No. Log $K_{OW} = 3.7$
	BCF ≥ 5000		No Whole Fish BCF = 78
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No. Does not meet all four TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

[5] Source of the active ingredient endpoints: REG2006-11, *Tebuconazole*.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for tebuconazole is adequate to define the majority of toxic effects that may result from exposure. In subchronic and chronic studies on laboratory animals, the primary targets were the liver, spleen and the adrenal glands. There was no evidence of carcinogenicity in rats after longer-term dosing with tebuconazole; however, an increase in liver tumours was noted in mice. There was evidence of increased sensitivity of the young in the reproductive toxicity, developmental toxicity and developmental neurotoxicity studies. Tebuconazole was not considered to be a neurotoxicant and there were no effects on the immune or endocrine systems. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixers, loaders and applicators handling Mirage Stressgard and workers re-entering treated turfgrass in sod farms and golf courses are not expected to be exposed to levels of tebuconazole that will result in health risks of concern when Mirage Stressgard is used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Exposure to the general public re-entering treated golf courses is not expected to result in health risks of concern when Mirage Stressgard is used according to label directions.

Please refer to Regulatory Note REG2006-11, *Tebuconazole* and Evaluation Reports under Application Numbers 2007-8784 and 2013-1019 for previously reviewed data regarding the food residue exposure assessment. The use of tebuconazole on turfgrass in golf courses and sod farms does not constitute a health risk of concern for chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

7.2 Environmental Risk

Current environmental risk assessment methodology was used to conduct the screening level and refined risk assessment for tebuconazole fungicide use on turf, including an evaluation of risk from spray drift and runoff. Using the previously evaluated information in REG2006-11, *Tebuconazole* as well as the additional environmental fate and ecotoxicological information provided, it has been determined that there are potential risks to non-target terrestrial plants, birds, small wild mammals and aquatic organisms. It has been determined that aquatic spray buffer zones of 5 m in width and terrestrial spray buffer zones of 2 m in width are adequate to mitigate risk to non-target organisms resulting from tebuconazole spray drift resulting from use on turf by ground application equipment. Spray buffer zones will not mitigate run-off. To reduce the potential for run-off of tebuconazole to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to run-off and when heavy rain is forecasted are required. In addition, a vegetative strip between the area and the edge of a water body is recommended to reduce run-off of tebuconazole to aquatic areas.

7.3 Value

The value information provided to support the registration of Mirage Stressgard was primarily in the form of efficacy trials as well as use history of the product in the United States. This information demonstrated that tebuconazole is effective in controlling economically important summer and winter turfgrass diseases. The level of efficacy against the pathogens in the trials was deemed acceptable and comparable to the commercial standards tested. The registration of Mirage Stressgard will provide turf managers with a new and effective group 3 active ingredient which can be used as a rotational option with other mode of action fungicides to control or suppress listed diseases, as well as contribute to resistance management.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Folicur Technical Fungicide and Mirage Stressgard, containing the technical grade active ingredient tebuconazole, for control of diseases of turfgrass on golf courses and sod farms.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

>	greater than
≥	greater than or equal to
<	less than
≤	less than or equal to
Φ	Phi
λ	wavelength
µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ALAT	alanine aminotransferase
Appls	applications
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
atm	atmosphere
ATPD	area treated per day
BC	British Columbia
BCF	bioconcentration factor
bw	body weight
CAF	Composite Assessment Factor
CAS	Chemical Abstracts Service
CBI	confidential business information
CEPA	*Canadian Environmental Protection Act*
cm	centimetres
d	day(s)
DACO	data code
DEEM-FCID	Dietary Exposure Evaluation Model
DF	dry flowable
DFOP	double first-order in parallel
DFR	dislodgeable foliar residue
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
EIIS	USEPA Ecological Incident Information System
ELS	early life stage
FDA	*Food and Drugs Act*
g	gram
ha	hectare(s)
Hg	mercury
hr	hour
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{oc}	organic-carbon partition coefficient

K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOEL	lowest-observed-effect-level
LOC	level of concern
m	metre(s)
mg	milligram
mL	millilitre
mm	millimetre(s)
mPa	megapascals
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
ORETF	Outdoor Residential Exposure Task Force
Pa	pascals
PCPA	*Pest Control Product Act*
PHED	Pesticide Handlers Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PWC	Pesticide in Water Calculator
Reg. No.	Registration Number
REI	restricted entry interval
RQ	risk quotient
SFO	single first-order
SOP	standard operating procedure
STMdR	supervised trial median residue
$t_{1/2}$	half-life
TC	transfer coefficient
TEU	tebuconazole
TSMP	Toxic Substances Management Policy
TTR	transferable turf residue
US	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WG	wettable granule

Appendix I Tables and Figures

Table 1 Toxicology Endpoints for Use in Health Risk Assessment for Tebuconazole

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	CAF[1] or Target MOE[2]
Acute dietary, females aged 13-49	NOAEL = 10	Mouse developmental toxicity	Increased post-implantation loss and increased external malformations (wart-like growths, runt, acrania).	300
	ARfD = 0.03			
Chronic Dietary	NOAEL = 2.96	1-year dog oral toxicity	Increased hypertrophy of adrenal zona fasciculata and fatty vacuoles in adrenal zona glomerulosa cells.	100
	ADI = 0.03			
Short-term to Intermediate-term Inhalation	NOAEL = 10	Mouse developmental toxicity	Increased post-implantation loss and increased external malformations (wart-like growths, runt, acrania).	300
Short-term to Intermediate-term Dermal	NOAEL = 275	Mouse developmental toxicity	Increased alanine aminotransferase and increased relative adrenal weights in maternal animals. Palatoschisis, bipartite sternebrae, non-ossification of forelimb distal phalanx and supernumerary ribs in foetuses.	300
Oral Short- and Intermediate-term aggregate assessment (females 13-49)	NOAEL = 10	Oral Mouse developmental toxicity	Increased post-implantation loss and increased external malformations (wart-like growths, runt, acrania).	300
Dermal Short- and Intermediate-term aggregate assessment (females 13-49)	NOAEL = 275	Dermal Mouse developmental toxicity	Palatoschisis, bipartite sternebrae, non-ossification of forelimb distal phalanx and supernumerary ribs in foetuses.	300
Combined Inhalation and Dermal Occupational Exposure Endpoints	NOAEL = 30 NOAEL = 275	Mouse developmental toxicity Mouse developmental toxicity	Palatoschisis and exencephaly	300
Cancer	Evidence of liver tumours in mice. The endpoints selected for non-cancer risk assessment are protective of this finding.			

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessment
[2] MOE refers to a target MOE for occupational and residential assessments

Table 2 Food Residue Chemistry Overview of Risk Assessment

DIETARY RISK FROM FOOD AND WATER		
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**
		Food and Water
Refined chronic (non-cancer and cancer) dietary exposure analysis **ADI = 0.03 mg/kg bw/day** **Estimated chronic drinking water concentration = 113 Φg/L**	**All infants < 1 year**	35.9
	Children 1–2 years	19.9
	Children 3 to 5 years	16.6
	Children 6–12 years	12.3
	Youth 13–19 years	10.3
	Adults 20–49 years	13.8
	Adults 50+ years	12.9
	Females 13-49 years	13.4
	Total population	13.7
Intermediate Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.03 mg/kg bw** **Estimated acute drinking water concentration = 113 Φg/L**	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**
		Food and Water
	Females 13-49 years	58.3

Table 3 Fate and Behaviour of Tebuconazole in the Terrestrial Environment – New Study Data (Additional to REG2006-11, *Tebuconazole*)

Property	Test Substance	Value	Comments	Reference (PMRA No.)
Field dissipation in Canada – EcoRegion 9.2: Minto, Manitoba	Folicur 432 F Foliar fungicide	DT_{50} (DFOP) = 157, 52.1 and 88.5 days for 1st, 2nd and 3rd application year. Slow $t_{1/2}$ (2nd dissipation phase = 1660, 295 and 173 days for 1st, 2nd and 3rd application year. Minor TP = 1, 2, 4-Triazole Bare plot carryover = 44.28 % (1st year), 25.58% (2nd year), 20.81% (3rd year) and 15.3% (4th year). Cropped plot carryover: 73.69% (1st year), 65.71% (2nd year), 51.86% (3rd year) and 44.59% (4th year).	Tebuconazole dissipated in a bi-phasic manner. Tebuconazole is moderately persistent to persistent and will carryover particularly when applied on turf surface.	Applicant Study: PMRA # 1522419

Field dissipation in Northern US – EcoRegion 8.1: New York	LYNX 25 DF formulation (25% ai.)	No bare plots. DT_{50} for turf plots = 1249 days (SFO) TP: Not monitored	Tebuconazole is persistent when applied on turf.	Applicant Study: PMRA #2456683
Field dissipation in Northern US – EcoRegion 8.1: Wisconsin	LYNX 25 formulation (25% a.i.)	No bare plots. DT_{50} for turf plots = 163.2 days (SFO) TP: 1,2,4 Triazole	Tebuconazole is persistent when applied on turf.	Applicant Study: PMRA #2456680

Table 4 Maximum EECs Derived from the Multiple Applications Scenario of Mirage Stressgard

Max Seasonal Application Rate From Label (g a.i./ha)	Max Seasonal App Rate: Including dissipation between applications (g a.i./ha)	Terrestrial EEC		Aquatic EEC	
		Foliar exposure (g a.i./ha)	Soil exposure (mg a.i./kg soil)	15 cm water (mg a.i./L)	80 cm water (mg a.i./L)
1536 g a.i./ha x 2 apps, 14-day interval	1969.55 (foliar) 3052.74 (soil) 3058.97 (aquatic)	1969.55	1.36	2.04	0.38

Table 5 Toxicity of Tebcuonazole to non-target terrestrial species – Updated Values and New Study Data (Additional to REG2006-11, Tebuconazole)

Organism	Exposure	Test substance	Endpoint value and Comments	Degree of Toxicity[1]	Reference[2] (PMRA No.)
Birds					
Bobwhite quail	Dietary	Tebuconazole	LD_{50} > 1014.3 mg a.i./kg body weight NOEL < 1014.3 mg a.i./kg body weight based on reduced body weight	Practically non-toxic	REG2006-11, *Tebuconazole*, values converted from concentration to dose
Mallard duck	Dietary	Tebuconazole	LD_{50} > 2107.7 mg a.i./kg body weight/day NOEL < 2107.7 mg a.i./kg body weight/day based on reduced body weight	Slightly toxic	REG2006-11, *Tebuconazole*, values converted from concentration to dose
	Reproduction	Tebuconazole	NOEL = 8.76 mg a.i./kg body weight, the highest test dose	N/A	REG2006-11, *Tebuconazole*, value converted from concentration to dose
Mammals					
Rat	Reproduction (Multi-generation dietary)	Tebuconazole	NOEL = 24.4 mg a.i./kg body weight/day (females) NOEL = 30.9 mg a.i./kg body weight/day (males) based on decreased pup	N/A	REG2006-11, *Tebuconazole*, value selected for use in current risk assessment updated

			viability and lactation index (survival during lactation) and decreased pup body weight		to reflect ecologically relevant endpoints
Vascular Plants					
Vascular plant	Seedling emergence	Folicur 432F Foliar Fungicide	EC_{25} = 63.3 g a.i./ha (tomato biomass) NOEC = 11.3 g a.i./ha (tomato shoot length)		Applicant Study: PMRA # 1522420

[1] Degree of toxicity: USEPA classification, where applicable
[2] Reference: Where there is additional text following "REG-2006-11", this means that the same study data were used as in REG2006-11, *Tebuconazole*, but ecotoxicity endpoint values have been updated. Where PMRA #s are given for applicant study, this means that these are data reviewed subsequent to REG2006-11, *Tebuconazole*.

Table 6 Toxicity of Tebuconazole to Non-Target Aquatic Species – New Study Data (Additional to REG2006-11, *Tebuconazole*)

Organism	Exposure	Test Substance	Endpoint Value	Degree of Toxicity	Reference (PMRA No.)
Freshwater Species					
Chironomid - Midge (*Chironomus riparius*)	Chronic	Tebuconazole	**Based on emergence:** 28-d EC_{50} = 2.97 mg a.i./L NOEC = 1.52 mg a.i./L **Based on development rate:** 28-d EC_{50} = 1.52-2.59 mg a.i./L NOEC = 0.833 mg a.i./L	N/A	Applicant Study: PMRA # 1487904
Marine Species					
Marine Fish – Sheepshead minnow (*Cyprinodon variegatus*)	Acute	Tebuconazole	LC_{50} > 7.82 mg a.i./L NOEC = 2.07 mg a.i./L	Moderately toxic (USEPA Classification System)	Applicant Study: PMRA # 1522442
Marine Algae – Saltwater diatom (*Skeletonema costatum*)	Acute	Tebuconazole	**Based on cell density**: 96-h EC_{50} = 0.24 mg a.i./L **Based on cumulative biomass**: 96-h EC_{50} = 0.19 mg a.i./L **Based on growth rate**: 96-h EC_{50} = 0.14 mg a.i./L NOEC (all endpoints) = 0.05 mg a.i./L	N/A	Applicant Study: PMRA # 1453965

Table 7 Screening Level Risk Assessment for Non-Target Terrestrial Invertebrates and Plants Exposed to Tebuconazole (Maximum Multiple Application Scenario: 1536 g a.i./ha × 2 apps)

Organism	Ecotox Endpoint Descriptor: Substance	Ecotox Endpoint Value	Converted Ecotox Endpoint Value[c]	Enviro Exposure (EEC) Value	Enviro Exposure (EEC) Units	RQ	LOC Exceeded
TERRESTRIAL INVERTEBRATES							
Exposure to treated soil							
Earthworm [a]	Acute Mortality (LC_{50}): TEU	1381	690.5	1.36	mg a.i./kg soil	0.0020	No
	Sub-lethal Effects (NOEC): TEU	178	178	1.36	mg a.i./kg soil	0.0076	No
TERRESTRIAL VASCULAR PLANTS							
Exposure to direct overspray (vegetative vigour) and to treated soil (seedling emergence)							
Plants	Vegetative Vigour [a] (EC_{25}): Folicur 432F	> 453	453	1969.55	g a.i./ha	4.35	Yes
	Seedling Emergence [b] (EC_{25}): Tebuconazole SC 432 G (Folicur 432F)	63.3	0.028	1.36	mg a.i./kg soil	48.57	Yes

[a] Ecotoxicity Values for Earthworm and Vegetative Vigour from REG2006-11, *Tebuconazole*

[b] Ecotoxicity Values for Seedling Emergence from previous evaluation of conversion to full registration for foliar uses. This value was converted to a soil concentration with the following equation:

63.3 g a.i./ha ÷100 ÷ 15 cm soil depth ÷ 1.5 g/cm^3 bulk density = 0.028 mg a.i./kg soil

[c] Conversions for acute (LC_{50}) values: 1/2 for earthworms

Table 8 Refined Risk Assessment for Non-Target Terrestrial Plants Exposed to Drift of Mirage Stressgard

	Vegetative Vigour	Seedling Emergence
ON FIELD Screening Level Information		
Ecotox Endpoint	453	0.028
EEC	1969.55	1.36
Screening RQ	4.35	48.57
Screening LOC Exceeded	Yes	Yes

OFF - FIELD Ground Boom (Field) Sprayer Medium (6% drift)		
EEC Refined for Drift	118.17	0.08
RQ Refined for Drift	0.26	2.91
LOC for Drift Exceeded	No	Yes

Table 9 Screening Level Risk Assessment for Birds and Mammals based on Multiple Applications of Tebuconazole (1536 g a.i./ha × 2 apps)

	Toxicity (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)				
Acute	120.00	Insectivore	160.31	1.34
Reproduction	8.76	Insectivore	160.31	18.30
Medium Sized Bird (0.1 kg)				
Acute	120.00	Insectivore	125.11	1.04
Reproduction	8.76	Insectivore	125.11	14.28
Large Sized Bird (1 kg)				
Acute	120.00	Herbivore (short grass)	80.81	0.67
Reproduction	8.76	Herbivore (short grass)	80.81	9.23
Small Mammal (0.015 kg)				
Acute	285.00	Insectivore	92.21	0.32
Reproduction	24.40	Insectivore	92.21	3.78
Medium Sized Mammal (0.035 kg)				
Acute	285.00	Herbivore (short grass)	178.83	0.63
Reproduction	24.40	Herbivore (short grass)	178.83	7.33
Large Sized Mammal (1 kg)				
Acute	285.00	Herbivore (short grass)	95.56	0.34
Reproduction	24.40	Herbivore (short grass)	95.56	3.92

Table 10 Expanded Assessment of Risk for Birds based on Multiple Applications of Tebuconazole (1536 g a.i./ha × 2 apps)

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Bird (0.02 kg)										
Acute	120.00	Insectivore	160.31	1.34	9.62	0.08	110.69	0.92	6.64	0.06
	120.00	Granivore (grain and seeds)	24.81	0.21	1.49	0.01	11.83	0.10	0.71	0.01
	120.00	Frugivore (fruit)	49.62	0.41	2.98	0.02	23.67	0.20	1.42	0.01
Dietary	101.43	Insectivore	160.31	1.58	9.62	0.09	110.69	1.09	6.64	0.07
	101.43	Granivore (grain and seeds)	24.81	0.24	1.49	0.01	11.83	0.12	0.71	0.01
	101.43	Frugivore (fruit)	49.62	0.49	2.98	0.03	23.67	0.23	1.42	0.01
Reproduction	**8.76**	**Insectivore**	**160.31**	**18.30**	**9.62**	**1.10**	**110.69**	**12.64**	**6.64**	**0.76**
	8.76	**Granivore (grain and seeds)**	**24.81**	**2.83**	**1.49**	**0.17**	**11.83**	**1.35**	**0.71**	**0.08**
	8.76	**Frugivore (fruit)**	**49.62**	**5.66**	**2.98**	**0.34**	**23.67**	**2.70**	**1.42**	**0.16**
Medium Sized Bird (0.1 kg)										
Acute	120.00	Insectivore	125.11	1.04	7.51	0.06	86.38	0.72	5.18	0.04
	120.00	Granivore (grain and seeds)	19.36	0.16	1.16	0.01	9.23	0.08	0.55	0.00
	120.00	Frugivore (fruit)	38.72	0.32	2.32	0.02	18.47	0.15	1.11	0.01
Dietary	101.43	Insectivore	125.11	1.23	7.51	0.07	86.38	0.85	5.18	0.05
	101.43	Granivore (grain and seeds)	19.36	0.19	1.16	0.01	9.23	0.09	0.55	0.01
	101.43	Frugivore (fruit)	38.72	0.38	2.32	0.02	18.47	0.18	1.11	0.01
Reproduction	**8.76**	**Insectivore**	**125.11**	**14.28**	**7.51**	**0.86**	**86.38**	**9.86**	**5.18**	**0.59**
	8.76	**Granivore (grain and seeds)**	**19.36**	**2.21**	**1.16**	**0.13**	**9.23**	**1.05**	**0.55**	**0.06**
	8.76	**Frugivore (fruit)**	**38.72**	**4.42**	**2.32**	**0.27**	**18.47**	**2.11**	**1.11**	**0.13**
Large Sized Bird (1 kg)										
Acute	120.00	Insectivore	36.53	0.30	2.19	0.02	25.22	0.21	1.51	0.01
	120.00	Granivore (grain and	5.65	0.05	0.34	0.00	2.70	0.02	0.16	0.00

		seeds)								
	120.00	Frugivore (fruit)	11.31	0.09	0.68	0.01	5.39	0.04	0.32	0.00
	120.00	Herbivore (short grass)	80.81	0.67	4.85	0.04	28.70	0.24	1.72	0.01
	120.00	Herbivore (long grass)	49.34	0.41	2.96	0.02	16.11	0.13	0.97	0.01
	120.00	Herbivore (Broadleaf plants)	74.77	0.62	4.49	0.04	24.72	0.21	1.48	0.01
Dietary	101.43	Insectivore	36.53	0.36	2.19	0.02	25.22	0.25	1.51	0.01
	101.43	Granivore (grain and seeds)	5.65	0.06	0.34	0.00	2.70	0.03	0.16	0.00
	101.43	Frugivore (fruit)	11.31	0.11	0.68	0.01	5.39	0.05	0.32	0.00
	101.43	Herbivore (short grass)	80.81	0.80	4.85	0.05	28.70	0.28	1.72	0.02
	101.43	Herbivore (long grass)	49.34	0.49	2.96	0.03	16.11	0.16	0.97	0.01
	101.43	Herbivore (Broadleaf plants)	74.77	0.74	4.49	0.04	24.72	0.24	1.48	0.01
Reproduction	**8.76**	**Insectivore**	**36.53**	**4.17**	**2.19**	**0.25**	**25.22**	**2.88**	**1.51**	**0.17**
	8.76	**Granivore (grain and seeds)**	**5.65**	**0.65**	**0.34**	**0.04**	**2.70**	**0.31**	**0.16**	**0.02**
	8.76	**Frugivore (fruit)**	**11.31**	**1.29**	**0.68**	**0.08**	**5.39**	**0.62**	**0.32**	**0.04**
	8.76	**Herbivore (short grass)**	**80.81**	**9.23**	**4.85**	**0.55**	**28.70**	**3.28**	**1.72**	**0.20**
	8.76	**Herbivore (long grass)**	**49.34**	**5.63**	**2.96**	**0.34**	**16.11**	**1.84**	**0.97**	**0.11**
	8.76	**Herbivore (Broadleaf plants)**	**74.77**	**8.54**	**4.49**	**0.51**	**24.72**	**2.82**	**1.48**	**0.17**

Table 11 Expanded Assessment of Risk for Mammals based on Multiple Applications of Tebuconazole (1536 g a.i./ha × 2 apps)

			Maximum nomogram residues				Mean nomogram residues			
			On-field		Off Field		On-field		Off Field	
	Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Mammal (0.015 kg)										
Acute	285.00	Insectivore	92.21	0.32	5.53	0.02	63.67	0.22	3.82	0.01
	285.00	Granivore (grain and seeds)	14.27	0.05	0.86	0.00	6.81	0.02	0.41	0.00
	285.00	Frugivore (fruit)	28.54	0.10	1.71	0.01	13.61	0.05	0.82	0.00
Reproduction	24.40	Insectivore	92.21	3.78	5.53	0.23	63.67	2.61	3.82	0.16
	24.40	Granivore (grain and seeds)	14.27	0.58	0.86	0.04	6.81	0.28	0.41	0.02
	24.40	Frugivore (fruit)	28.54	1.17	1.71	0.07	13.61	0.56	0.82	0.03
Medium Sized Mammal (0.035 kg)										
Acute	285.00	Insectivore	80.83	0.28	4.85	0.02	55.81	0.20	3.35	0.01
	285.00	Granivore (grain and seeds)	12.51	0.04	0.75	0.00	5.97	0.02	0.36	0.00
	285.00	Frugivore (fruit)	25.02	0.09	1.50	0.01	11.93	0.04	0.72	0.00
	285.00	Herbivore (short grass)	178.83	0.63	10.73	0.04	63.51	0.22	3.81	0.01
	285.00	Herbivore (long grass)	109.19	0.38	6.55	0.02	35.65	0.13	2.14	0.01
	285.00	Herbivore (forage crops)	165.46	0.58	9.93	0.03	54.70	0.19	3.28	0.01
Reproduction	24.40	Insectivore	80.83	3.31	4.85	0.20	55.81	2.29	3.35	0.14
	24.40	Granivore (grain and seeds)	12.51	0.51	0.75	0.03	5.97	0.24	0.36	0.01
	24.40	Frugivore (fruit)	25.02	1.03	1.50	0.06	11.93	0.49	0.72	0.03
	24.40	Herbivore (short grass)	178.83	7.33	10.73	0.44	63.51	2.60	3.81	0.16
	24.40	Herbivore (long grass)	109.19	4.48	6.55	0.27	35.65	1.46	2.14	0.09
	24.40	Herbivore (broadleaf plants)	165.46	6.78	9.93	0.41	54.70	2.24	3.28	0.13

Large Sized Mammal (1 kg)										
Acute	285.00	Insectivore	43.19	0.15	2.59	0.01	29.82	0.10	1.79	0.01
	285.00	Granivore (grain and seeds)	6.68	0.02	0.40	0.00	3.19	0.01	0.19	0.00
	285.00	Frugivore (fruit)	13.37	0.05	0.80	0.00	6.38	0.02	0.38	0.00
	285.00	Herbivore (short grass)	95.56	0.34	5.73	0.02	33.94	0.12	2.04	0.01
	285.00	Herbivore (long grass)	58.34	0.20	3.50	0.01	19.05	0.07	1.14	0.00
	285.00	Herbivore (Broadleaf plants)	88.41	0.31	5.30	0.02	29.23	0.10	1.75	0.01
Reproduction	24.40	Insectivore	43.19	1.77	2.59	0.11	29.82	1.22	1.79	0.07
	24.40	Granivore (grain and seeds)	6.68	0.27	0.40	0.02	3.19	0.13	0.19	0.01
	24.40	Frugivore (fruit)	13.37	0.55	0.80	0.03	6.38	0.26	0.38	0.02
	24.40	Herbivore (short grass)	95.56	3.92	5.73	0.23	33.94	1.39	2.04	0.08
	24.40	Herbivore (long grass)	58.34	2.39	3.50	0.14	19.05	0.78	1.14	0.05
	24.40	Herbivore (Broadleaf plants)	88.41	3.62	5.30	0.22	29.23	1.20	1.75	0.07

Table 12 Screening Level Risk Assessment for Non-Target Aquatic Organisms Exposed to Multiple Applications of Tebuconazole (1536 g a.i./ha × 2 apps, 14-day interval)

Organism [a]	Ecotox Endpoint Descriptor	Ecotox Endpoint Value (mg a.i./L)	Converted Ecotox Value [b] (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC Exceeded
FRESHWATER SPECIES						
Freshwater Pelagic Invertebrate: Water flea (*Daphnia magna*)	acute (48 hour NOEC)	0.74	0.74	0.382	0.52	No
	chronic (21 day EC_{50})	0.33	0.165	0.382	2.32	Yes
	chronic (21 day NOEC)	0.12	0.12	0.382	3.18	Yes
Freshwater Benthic Invertebrate: Midge (*Chironomus riparius*)	emergence (28 day EC_{50})	2.97	1.485	0.382	0.26	No
	emergence (28 day NOEC)	1.52	1.52	0.382	0.25	No
	development rate	1.52	0.76	0.382	0.50	No

	(28 day EC_{50})					
	development rate (28 day NOEC)	0.833	0.833	0.382	0.46	No
Rainbow Trout (*Oncorhynchus mykiss*)	acute (96 hour LC_{50})	4.4	0.44	0.382	0.87	No
	acute (96 hour NOEC)	1.5	1.5	0.382	0.25	No
	chronic: early life stages (60 day NOEC)	0.012	0.012	0.382	31.83	Yes
Bluegill Sunfish (*Lepomis macrochirus*)	acute (96 hour LC_{50})	5.7	0.57	0.382	0.67	No
	acute (96 hour NOEC)	1.4	1.4	0.382	0.27	No
Freshwater Green Alga (*Scenedesmus subspicatus*)	acute biomass (96 hour EC_{50})	1.64	0.82	0.382	0.47	No
	acute growth rate (96 hour EC_{50})	4.01	2.005	0.382	0.19	No
Freshwater Green Alga (*Selenastrum capricornutum*)	acute cell density (96 hour EC_{50})	2.83	1.415	0.382	0.27	No
	acute cell density (96 hour NOEC)	2.46	2.46	0.382	0.16	No
Freshwater Macrophyte (*Lemna gibba G3*)	acute frond number (14 day EC_{50})	0.14	0.0722	0.382	5.29	Yes
	acute biomass (14 day EC_{50})	0.18	0.0899	0.382	4.25	Yes
Amphibians (fish data used as surrogate)	Rainbow trout acute (LC_{50})	4.4	0.44	2.039	4.63	Yes
	Rainbow trout ELS (NOEC)	0.012	0.012	2.039	169.92	Yes
MARINE SPECIES						
Marine Invertebrate: Mysid shrimp (*Mysidopsis bahia*)	acute (96 hour LC_{50})	0.45	0.225	0.382	1.70	Yes
	acute (96 hour	0.3	0.3	0.382	1.27	Yes

	NOEC)					
Marine Invertebrate: Eastern oyster (*Crassostrea virginica*)	acute (96 hour LC_{50})	3	1.5	0.382	0.25	No
	acute (96 hour NOEC)	1.7	1.7	0.382	0.22	No
Marine Fish: Sheepshead minnow (*Cyprinodon variegatus*)	acute (96 hour LC_{50})	7.82	0.782	0.382	0.49	No
	acute (96 hour NOEC)	2.07	2.07	0.382	0.18	No
	chronic: full life cycle (24 weeks LD_{50})	0.098	0.0978	0.382	3.91	Yes
	chronic: full life cycle (24 weeks NOEC)	0.044	0.0436	0.382	8.76	Yes
Marine alga: Diatom (*Skeletonema costatum*)	acute cell density (96 h hour EC_{50})	0.24	0.12	0.382	3.18	Yes
	acute biomass (96 hour EC_{50})	0.19	0.095	0.382	4.02	Yes
	acute biomass (96 hour EC_{50})	0.14	0.07	0.382	5.46	Yes
	all endpoints (96 hour NOEC)	0.05	0.05	0.382	7.64	Yes

a Ecotoxicity Values for midge, sheepshead minnow, and marine diatom previously reviewed in support of conversion submissions (See Table 6). Ecotoxicity Values for all remaining aquatic organisms from REG2006-11, Tebuconazole.

b Conversions for acute (LC50/EC50) values:1/10 for fish and amphibians; 1/2 for algae, macrophytes pelagic and benthic invertebrates. No conversion required for chronic (NOEC) values.

Table 13 Refined Risk Assessment for Sensitive Non-Target Aquatic Organisms Exposed to Drift of Mirage Stressgard

	ORGANISM							
	Daphnia magna (chronic: 21 day)	Rainbow Trout (ELS: 60 day)	*Lemna gibba* (acute: 14 day)	Amphibian (acute: 96 hour)	Amphibian (chronic: 21 day)	Mysid Shrimp (acute: 96 hour)	Sheepshead minnow (chronic: 24 weeks)	Marine Diatom (acute: 96 hour)
Screening Level Information [a]								
Converted Ecotox Endpoint (mg/L)	0.12	0.012	0.0722	0.44	0.012	0.225	0.0436	0.07
Screening Level EEC (mg/L)	0.382	0.382	0.382	2.039	2.039	0.382	0.382	0.382
Screening Level RQ	3.18	31.83	5.29	4.63	169.92	1.70	8.76	5.46
Ground Boom (Field) Sprayer Medium (6% drift)								
EEC Refined for Drift (mg/L)	0.023	0.023	0.023	0.122	0.122	0.023	0.023	0.023
RQ Refined for Drift [b]	0.191	1.910	0.317	0.278	10.195	0.102	0.526	0.327
Drift LOC Exceeded	No	Yes	No	No	Yes	No	No	No

a Organism and Exposure for which the level of concern (LOC) was exceeded at the screening level.
b Refined Risk Quotient = Modified (Drift) EEC value ÷ Ecotoxicity Endpoint of Concern

Table 14 Level 1 Aquatic Ecoscenario Modelling EECs (µg a.i./L) for Tebuconazole in a Water Body 0.8 m Deep, Excluding Spray Drift

Region	EEC (µg a.i./L)							
	Peak	96-hour	21-day	60-day	90-day	Yearly	Peak (in pore water)	21-d (in pore water)
2 × 1.536 kg a.i./ha, at 14-day interval								
BC	112	111	109	105	104	100	100	100
Prairie	52	52	49	47	46	42	43	43
ON	35	35	35	35	35	31	33	33
QC	42	41	40	40	40	37	38	38
Atlantic	54	53	51	50	50	46	49	49

Table 15 Level 1 Aquatic Ecoscenario Modelling EECs (µg a.i./L) for Tebuconazole in a Water Body 0.15 m Deep, Excluding Spray Drift

Region	EEC (µg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
2 × 1.536 kg a.i./ha, at 14-day interval						
BC	197	179	154	143	139	131
Prairie	132	105	74	64	62	56
ON	108	85	50	46	46	42
QC	128	101	63	53	53	49
Atlantic	156	122	77	66	66	61

Table 16 Refined Risk Assessment for Sensitive Non-Target Aquatic Organisms Exposed to Run-off of Mirage Stressgard

	Daphnia magna (chronic: 21 day)	Rainbow Trout (ELS: 60 day)	*Lemna gibba* (acute: 14 day)	Amphibian (acute: 96 hour)	Amphibian (chronic: 21 day)	Mysid Shrimp (acute: 96 hour)	Sheepshead minnow (chronic: 24 weeks)	Marine Algae (acute: 96 hour)
Screening Level Information [a]								
Converted Ecotox Endpoint (mg/L)	0.12	0.012	0.0722	0.44	0.012	0.225	0.0436	0.07
Screening Level EEC (mg/L)	0.382	0.382	0.382	2.039	2.039	0.382	0.382	0.382
Screening Level RQ	3.18	31.83	5.29	4.63	169.92	1.70	8.76	5.46
RUN-off								
EEC Refined for Runoff (mg/L)	0.109	0.105	0.109	0.179	0.154	0.111	0.111	0.111
RQ Refined for Runoff [b]	0.908	8.750	1.510	0.407	12.833	0.493	2.546	1.586
Runoff LOC Exceeded	No	Yes	Yes	No	Yes	No	Yes	Yes

a Organism and Exposure for which the level of concern (LOC) was exceeded at the screening level.
b Refined Risk Quotient = Modelled (Runoff) EEC value ÷ Ecotoxicity Endpoint of Concern

Table 17 Size of Buffer Zones Required for Foliar Application of Mirage Stressgard

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Turfgrass on golf course and sod farms	5	1	1	1	2

Table 18 List of Supported Uses

Supported Uses
Control of dollar spot (*Sclerotinia homoeocarpa*) on turfgrass (golf courses and sod farms) when applied at 32-64 mL per 100m^2, with an application interval of 14-21 days. Apply the higher rate with the 21 day application interval.
Control of brown patch (*Rhizoctonia solani*) on turfgrass (golf courses and sod farms) when applied at 32-64 mL per 100m^2, with an application interval of 14-21 day. Apply the higher rate with the 21 day application interval.
Control of Anthracnose (basal rot and foliar) (*Colletotrichum cereale*) on turfgrass (golf courses and sod farms) when applied at 32-64 mL per 100m^2, with an application interval of 14-21 days. Under severe disease pressure and basal rot infection, apply the higher rate and use the shortest interval.
Control of fairy ring *(Basidiomycetes)* on turfgrass (golf courses and sod farms) when applied at 32-64 mL per 100m^2, with an application interval of 14-21 days. Apply the highest rate with the shortest interval under severe disease pressure and where there is a prior history of disease.
Control of summer patch *(Magnaporthe poae)* on turfgrass (golf courses and sod farms) when applied at 32-64 mL per 100m^2, with an application interval of 14-28 days. Apply the highest rate with the shortest interval under severe disease pressure and where there is a prior history of disease.
Suppression of pink snow mould, (*Microdochium nivale)* on turfgrass (golf courses and sod farms) when applied at 30-60 mL per 100m^2, with one application before snow cover. Use the highest rate under severe under disease pressure and where there is a prior history of disease. Mirage Stressgard, applied as a solo product, is recommended where lower level of control is acceptable. For optimal pink snow mould control it is recommended to tank mix Mirage Stressgard with at least one of the following partners: Compass 50 WG at 6.1 g/100 m^2, Compass 50 WG + Daconil Ultrex at 6.1 g + 145 g/100 m^2
Control of grey snow mould *(Typhula incarnata and T. ishikariensis)* on turfgrass (golf courses and sod farms) when applied at 30-60 mL per 100m^2, with one application before snow cover. Use the highest rate under severe under disease pressure and where there is a prior history of disease. For optimal grey snow mould control it is recommended to tank mix Mirage Stressgard with at least one of the following partners: Compass 50 WG at 6.1 g/100 m^2, Compass 50 WG + Daconil Ultrex at 6.1 g + 145 g/100 m^2

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Table 1 Differences Between MRLs in Canada and in Other Jurisdictions

Please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website for the established MRLs for tebuconazole.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	References
2456634	2006, Product chemistry of Lynx Green, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.3.1, 3.3.2, 3.4.1, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4,3.5.5,3.5.6,3.5.7, 3.5.8, 3.5.9 CBI
2456632	2014, Tebuconazole SC Turf Fungicide Tier III Summary, DACO: 12.7, 4.1, 5.1,8.1, 8.2.1, 8.2.3.1, 8.2.4.1, 8.3.1, 9.1, 9.2.1, 9.3.1 ,9.5.1, 9.6.1, 9.8.1 CBI
2456638	2010, Storage Stability of Lynx with StressGard, DACO: 3.5.10,3.5.14 CBI
2497783	2015, Production Process of Tebuconazole SC 240 G, DACO: 3.2.2 CBI
2497784	2007, Storage Stability of Lynx Green SC, DACO: 3.5.10,3.5.14 CBI
2592034	2015, Mirage: Accelerated Storage Stability, DACO: 3.4.1,3.5.10,3.5.14 CBI
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2536554	2014, Capillary GC Determination of Tebuconazole, DACO: 3.4.1 CBI
2536555	2015, Enforcement Method(s) for Validation of Analytical Method C-10.10-12 Capillary GC Determination of Tebuconazole, DACO: 3.4.1 CBI

2.0 Human and Animal Health

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2115788	2008, Agricultural Reentry Task Force (ARTF). Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission #2006-0257.
1563654	1999, Exposure of Professional Lawn Care Workers During the Mixing and Loading of Dry and Liquid Formulations and the Liquid Application of Turf Pesticides Utilizing A Surrogate Compound, Appendix 4, OMA002. ORETF. Submission #2006-4038, DACO: 5.3,5.4
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3.0 Environment

1522419	2007, Terrestrial Field Dissipation of Tebuconazole in Canadian Soil, 2000, DACO: 8.3.2.1
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1522420 2007, Tebuconazole SC 432 G (Folicur 432 F) Effects on the seedling emergence and seedling growth of three species of non-target terrestrial plants (Tier 2), DACO: 9.8.4

1487904 2003, Influence of Tebuconazole (tech.) on Development and Emergence of Larvae of Chironomus riparius in a Water-Sediment System, DACO: 9.3.4

1522442 2007, Acute Toxicity of Tebuconazole to the Sheepshead Minnow (Cyprinodon variegatus) Under Static Conditions, DACO: 9.5.2.4

1453965 2003, Toxicity of Tebuconazole Technical to the Saltwater Diatom Skeletonema costatum, DACO: 9.8.3

4.0 Value

2497774 2015, Tebuconazole SC Turf Fungicide (containing 240g ai/L of tebuconazole) for the control of diseases in turfgrass. Response to deficiencies identified by PMRA in correspondence dated 20 November 2014, DACO: 10.2.3.3(D)

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B. Additional Information Considered

i) Published Information

1.0 Environment

2670217 Fantke, P., et al., 2014, Estimating Half-Lives for Pesticide Dissipation from Plants, Environmental Science & Technology. Volume 48: Pages 8588-8602.